

Amendment and Response to Office Action  
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Amendments To The Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

1

(Previously presented) A collagen material consisting of a matrix of a non-woven fabric multi-element structure of collagen fibers having ultra-fine fibers of collagen as its basic unit,

the matrix being filled with a substance having biocompatibility that can be degraded and absorbed in the body,

wherein said substance having biocompatibility that can be degraded and absorbed in the body is fibrous collagen fiber or a substance selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate, and a mixture of polyglycolic acid and polylactic acid,

wherein said non-woven fabric multi-element structure of collagen fibers is composed of collagen plate fibers having a diameter of 20-50  $\mu\text{m}$  randomly intertwined,

said plate fibers consisting of collagen fibers having a diameter of 5-8  $\mu\text{m}$ , wherein the collagen fibers overlap in the coaxial direction,

said fibers consisting of bundled rows of narrow collagen fibers having a diameter of 1-3  $\mu\text{m}$  alternately overlapping as warp and weft,

said narrow fibers consisting of bundled fine collagen fibers having a diameter of 30-70 nm, and

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said fine fibers consisting of ultra-fine collagen fibers having a diameter of 3-7 nm that are comprised of several bundled collagen molecules.

2. (Previously Presented) The collagen material according to claim 1, wherein said substance having biocompatibility that can be degraded and absorbed in the body and being filled into said matrix is fibrous collagen fiber containing ultra-fine fibers of collagen newly formed by performing a freezing and freeze-drying procedure to a hydrochloric acid solution of extracted collagen introduced into said matrix.

3. (Previously presented) The collagen material according to claim 1, wherein said substance having biocompatibility that can be degraded and absorbed in the body and being filled into said matrix is selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate, and a mixture of polyglycolic acid and polylactic acid, and is used as a mesh sheet or tube, or a non-woven fabric sheet or tube.

4. (Cancelled)

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4 5. (Currently Amended) A collagen material according to claim 1 in which the collagen fiber containing ultra-fine fibers of collagen is formed by performing a freezing, freeze-drying and thermal dehydration crosslinking procedure to a hydrochloric acid solution of extracted collagen is filled into a non-woven fabric matrix composed of that selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate, and a mixture of polyglycolic acid and polylactic acid.

6. (Cancelled)

7. (Cancelled)

5 6. (Previously presented) The collagen material according to claim 5, wherein said collagen fibers are composed of collagen plate fibers having a diameter of 20-50  $\mu\text{m}$  are randomly intertwined, said plate fibers are composed of collagen fibers having a diameter of 5-8  $\mu\text{m}$  overlap in the coaxial direction, said fibers are composed of bundled rows of narrow collagen fibers having a diameter of 1-3  $\mu\text{m}$  are alternately overlapping as warp and weft, said narrow fibers are composed of fine collagen fibers having a diameter of 30-70 nm are bundled, and said fine fibers are composed of ultra-fine collagen fibers having a diameter of 3-7 nm that are comprised of several collagen molecules are bundled.

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6 9. (Previously Presented) The collagen material according to claim 2, wherein said collagen material has one-point support tensile force of at least 30 N and rupture resistance tensile force of at least 65 N in the dry state, and has one-point support tensile force of at least 1.4 N and rupture resistance tensile force of at least 6.5 N in the wet state (for a thickness of 1mm).

7 10. (Previously presented) The collagen material according to any one of claims 3, 4, 5 or 6, wherein said collagen material has one-point support tensile force of at least 10 N and rupture resistance tensile force of at least 25 N in the dry state, and has one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm).

8 11. (Withdrawn - Currently amended) A production process of the [[a]] collagen material according to claim 1, comprising performing at least the steps indicated below in order:

- a. a collagen solution layer is formed by casting a hydrochloric acid solution of extracted collagen to a desired thickness;
- b. said collagen solution layer is temporarily frozen and held in that state for a desired amount of time followed by freeze-drying;
- c. thermal dehydration crosslinking is performed for a predetermined amount of time on said freeze-dried product;
- d. said hydrochloric acid solution of extracted collagen is introduced into the matrix of said thermal dehydration crosslinked product;

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e. the product introduced said solution of extracted collagen therein is temporarily frozen, held in that state for a predetermined amount of time and then freeze-dried;

g. said freeze-dried product is compressed; and,

i. thermal dehydration crosslinking is performed for a predetermined amount of time on that compressed product.

9 12. (Withdrawn) The process according to claim 11, wherein the following steps are performed in order between said step e and step g:

f1. said hydrochloric acid solution of extracted collagen is again introduced in the matrix of said freeze-dried product; and,

f2. the product introduced said extracted collagen solution therein is temporarily frozen, held in that state for a desired amount of time, and then freeze-dried.

10 13. (Withdrawn - Currently amended) The process according to claim claims 11 or 12, wherein the following step is performed between said steps g and i:

h1. a collagen solution layer is formed at a predetermined site on the surface of said compressed product.

11 14. (Withdrawn) The process according to claim 13, wherein the following step is performed between said steps h1 and i:

h2. said collagen solution layer is compressed.

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12 15. (Withdrawn - Currently amended) The process according to any one of claims claim 11 or 12 to 14, wherein the freezing and holding time during the freezing procedure in said steps b, e and f2 is 6-48 hours.

13 16. (Withdrawn - Currently amended) The process according to any one of claims claim 11 or 12 to 14, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen in said steps d and f1 is 0.5 wt% or less.

14 17. (Withdrawn - Currently amended) The process according to claim claims 13 or 14, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen for forming a collagen solution layer in said step h1 is 2.0 wt% or less.

15 18. (Withdrawn - Currently amended) The process according to claim claims 11 or 12, wherein casting of a hydrochloric acid solution of extracted collagen in said step a is divided into two procedures, and a mesh-like sheet or tube comprising a material selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate and a mixture of polyglycolic acid and polylactic acid is contained between both collagen solution layers between both casting procedures, said step g is performed after said step c while said step i is not performed.

16 19. (Withdrawn) The process according to claim 18, wherein the following steps are additionally performed after said step g:

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h3. a collagen solution layer or gelatin gel layer is formed on at least one side of said compressed product; and,

h4. thermal dehydration crosslinking is performed on the product formed said collagen solution layer or said gelatin gel layer.

17 20. (Withdrawn) The process according to claim 19, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen for forming said collagen solution layer is 2 wt% or less.

18 21. (Withdrawn) The process according to claim 19, wherein said gelatin concentration of the gelatin aqueous solution for forming said gelatin gel layer is 5-25 wt%.

19 22. (Withdrawn - Currently amended) A production process of the [[a]] collagen material according to claim 1, comprising performing at least the following steps in order:

j. a hydrochloric acid solution of extracted collagen is introduced into a non-woven fabric-like sheet-like or tube-like matrix comprising a material selected from the group consisting of polyglycolic acid, polylactic acid, copolymer of glycolic acid and lactic acid, polydioxanone, copolymer of glycolic acid and trimethylene carbonate and a mixture of polyglycolic acid and polylactic acid, followed by air-drying;

1. a collagen solution layer is formed on at least one side of the product introduced and air-dried said hydrochloric acid solution of extracted collagen;

o. a gelatin gel layer is formed on said collagen solution layer; and,

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p. thermal dehydration crosslinking is performed on the product formed said gelatin gel layer for predetermined amount of time.

*20* ~~23.~~ (Withdrawn) The process according to claim *22*, wherein the following step k is performed between said steps j and l, and the following step m is performed between said steps l and o:

k. the product introduced said extracted collagen is temporarily frozen, and that state is maintained for a predetermined amount of time followed by freeze-drying;

ml. the product on which said collagen solution layer is formed is temporarily frozen, and that state is maintained for a predetermined amount of time followed by freeze-drying; and,

m2. the product freeze-dried is compressed.

*21* ~~24.~~ (Withdrawn) The process according to claims *22* or *23*, wherein the following step n is performed between said steps l and o or between said steps m2 and o:

n. thermal dehydration crosslinking is performed for a predetermined amount of time on the product on which said collagen solution layer is formed or the product freeze-dried.

*22* ~~25.~~ (Withdrawn - Currently amended) The process according to any one of claims *22* or *23* to *24*, wherein the collagen concentration of the hydrochloric acid solution of extracted collagen in said steps j and l is 2.0 wt% or less.

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23 26. (Withdrawn - Currently amended) The process according to any one of claims  
19 or 20, wherein the gelatin concentration of the gelatin aqueous solution  
in said step o is 5-25 wt%.

24 27. (Withdrawn - Currently amended) The process according to any one of claims  
claim 11 or 12 to 17, wherein the collagen material produced has one-point support  
tensile force of at least 30 N and rupture resistance tensile force of at least 65 N in the  
dry state, and one-point support tensile force of at least 1.4 N and rupture resistance  
tensile force of at least 6.5 N in the wet state (for a thickness of 1 mm).

25 28. (Withdrawn - Currently amended) The process according to any one of claims  
claim 18 to 26, wherein the collagen material produced has one-point support tensile  
force of at least 10 N and rupture resistance tensile force of at least 25 N in the dry  
state, and one-point support tensile force of at least 5 N and rupture resistance tensile  
force of at least 25 N in the wet state (for a thickness of 1 mm).